Supreme Court, U.S.
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IN THE
SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1994

STANISLAW R. BURZYNSKI, M.D., Ph.D.

Petitioner

vs.

TRUSTEES OF THE NORTHWEST LAUNDRY AND DRY CLEANERS HEALTH & WELFARE TRUST

Respondent

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

APPENDIX TO PETITION FOR WRIT OF CERTIORARI

VOLUME I

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EXHIBIT "A"

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 93-2071

TRUSTEES OF THE NORTHWEST LAUNDRY AND DRY CLEANERS HEALTH & WELFARE TRUST FUND,

OCT 0 4 1994

Plaintiff-Appellee,

versus

STANISLAW R. BURZYNSKI,
Defendant-Appellant.

Appeal from the United States District Court for the Southern District of Texas

ON PETITION FOR REHEARING AND SUGGESTION FOR REHEARING EN BANC (Opinion July 28, 1994, 5 Cir., F.3d (October 4, 1994)

Before WISDOM, BARKSDALE and EMILIO M. GARZA, Circuit Judges. PER CURIAM:

(x) The Petition for Rehearing is DENIED and no member of this Panel nor Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc, (FRAP and Local Rule 35) the Suggestion(s) for Rehearing En Banc is also DENIED.

( ) The Petition for Rehearing is DENIED and the Court having been polled at the request of one of the members of the Court and a majority of the Judges who are in regular active service not having voted in favor, (FRAP and Local Rule 35)

the Suggestion for Rehearing En Banc is also DENIED.

( ) A member of the Court in active service having requested a poll on the reconsideration of this cause en banc, and a majority of the judges in active service not having voted in favor, rehearing en banc is DENIED.

ENTERED FOR THE COURT:

JOHN MINOR WISDOM

United States Circuit Judge

EXHIBIT "B"

United States Court of Appeals, Fifth Circuit.

No. 93-2071

TRUSTEES OF THE NORTHWEST LAUNDRY AND DRY CLEANERS HEALTH & WELFARE TRUST FUND,
Plaintiff-Appellee,

V.

Stanislaw R. BURZYNSKI, Defendant-Appellant.

July 28, 1994.

Appeal from the United States District Court for the Southern District of Texas.

Before WISDOM, BARKSDALE, and EMILIO M. GARZA, Circuit Judges. WISDOM, Circuit Judge:

Today we write the latest chapter in a medical iconoclast's long history of litigation over an unorthodox cancer treatment. The district court granted summary judgment for the plaintiff/appellee, the Northwest Laundry and Dry Cleaners Health & Welfare Trust Fund, an ERISA health insurance fund, after finding that the defendant/appellant, Dr. Stanislaw R. Burzynski, had defrauded the plaintiff and violated the terms of the health plan. We agree that the defendant may not trick the plaintiff into paying for an unlawful, unapproved drug. We AFFIRM.

I.

A. The Prior Litigation and Injunction

Dr. Stanislaw R. Burzynski is a Houston physician who developed an unorthodox treatment for cancer called antineoplastons".[1] The antineoplastons treatment has never been approved by the Food and Drug Administration ("FDA") or the Texas Department of Health. Dr. Burzynski's antineoplastons treatment has been the subject of frequent litigation.[2]

In 1983, the United States sued Dr. Burzynski's research organization, the Burzynski Research Institute, alleging several violations of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. On May 24, 1984, Judge Gabrielle K. McDonald of the United States District Court for the

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1 "Simply stated, antineoplastons are a special class of peptides, found in the blood, that combat neoplastons-abnormal cells or cancer cells." Gary Null, Gary Null's Complete Guide to Healing Your Body Naturally 95 (1988), attached to Def.'s Supplemental Mem. Supp. Mot. Dismiss or Change Venue, 3 Rec. 125.

2 In this Court alone, see In re Burzynski, 989 F.2d 733 (5th Cir.1993), modifying on rehearing Burzynski v. Aetna Life Ins. Co., 967 F.2d 1063 (5th Cir.1992); United States v. Burzynski Cancer Research Inst., 819 F.2d 1301 (5th Cir.), reh'g denied, 829 F.2d 1124 (5th Cir.1987), cert. denied, 484 U.S. 1065, 108 S.Ct. 1026, 98 L.Ed.2d 990 (1988).

Southern District of Texas partially granted the request of the United States for a permanent injunction. Judge McDonald's order prohibited Burzynski distributing his antineoplastons treatment in interstate commerce, but did not forbid intrastate distribution of the drug.[3]

B. The Antineoplastons Treatment of Huey Roberts

Huey Roberts, a resident of Oregon, developed cancer of the esophagus in 1986. Radiation treatments and chemotherapy did not reverse the progress of the disease. In 1988, Dr. Burzynski began administering a series of antineoplastons treatments to Roberts. After an initial series of treatments in Dr. Burzynski's Houston office, Roberts continued taking antineoplastons at his home in Oregon from a supply furnished by Dr. Burzynski. The antineoplastons treatments in Texas violated part of the Texas Food, Drug, and Cosmetic Act barring

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Judge McDonald's Final Judgment of Permanent Injunction was subject to the following proviso:

> Nothing contained herein shall be construed as restraining, enjoining or in any way prohibiting the Defendant's manufacture, processing, packing, holding, promotion, labeling, sale or distribution of the antineoplaston A10 or of any similar article however designated (provided articles are not falsely labeled or marked) when that manufacture, processing, packing, holding, promotion, labeling, sale or distribution is undertaken strictly and wholly intrastate.

the use of any non-FDA-approved drug in Texas.[4] The treatments in Oregon violated the permanent injunction Judge McDonald imposed on Dr. Burzynski in 1984. These treatments apparently proved ineffectual, and Huey Roberts discontinued antineoplastons therapy on July 4, 1989.

Huey Roberts was a beneficiary under the health plan of plaintiff/appellee Northwest Laundry and Dry Cleaners Health & Welfare Trust Fund ("the Fund"). Dr. Burzynski submitted claim forms to the Fund and received over $90,000 in reimbursements for the treatments he administered to Roberts.

When the Fund learned that it had reimbursed Dr. Burzynski f or illegal treatments, it brought this lawsuit in Oregon

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See Tex. Health & Safety Code Ann. S 431.114. This statute provides, in pertinent part, that

> (a) A person shall not sell, deliver, offer for sale, hold for sale or give away any new drug unless:
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> (1) an application with respect thereto has been approved and the approval has not been withdrawn under Section 505 of the federal Act; and
>
> (2) a copy of the letter of approval cm approvability issued by the Federal Food and Drug Administration is on file with the commissioner if the product is manufactured in this state.

The district court found that antineoplastons was a "new drug" within the meaning of § 431.114, and Dr. Burzynski does not contest the finding on appeal.

state court to try to get its money back. The Fund charged Dr. Burzynski with fraud and with violations of ERISA[5] and RICO.[6] Dr. Burzynski, invoking diversity jurisdiction, removed the case to the United States District Court for the District of Oregon, and on his motion for a change of venue, the case was transferred to the United States District Court for the Southern District of Texas.

On cross-motions for summary judgment, the district court entered summary judgment for Dr. Burzynski on the Fund's RICO claims and for the Fund on its fraud and ERISA claims. Dr. Burzynski appealed.

II.

A. The Fund's ERISA Claim

The ERISA plan under which Roberts was covered provided that:

> When medically necessary treatment is provided by a legally qualified physician for an illness or injury, and that physician is practicing within the scope of his license, payment will be made for expenses incurred for Hospital, Home and Office visits as shown in the Schedule of

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5 Employee Retirement Income Security Act, 29 U.S.C. SS 1001-1461.

6 Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. SS 1961-1968.

Benefits.[7]

To be "medically necessary" under the Plan, a treatment must meet two requirements, measured under Oregon law. First, the treatment must be "appropriate and consistent with the diagnosis (in accord with accepted standards of community practice)". Second, "medically necessary" treatments "could riot be omitted without adversely affecting the covered person's condition or the quality of medical care".[8]

Dr. Burzynski correctly points out that these requisites do not, by their express terms, hold all non-FDA-approved treatments medically "unnecessary". An Oregon court, however, construed nearly identical language in an insurance contract to bar coverage of an experimental cancer treatment. In Jacob

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7 A Group Health Program For Members Covered By The Northwest Laundry & Dry Cleaners Trust, Class 8, at 19, 2 Rec. 504.

8 Id. at 25, 2 Rec. 501. Although this definition appears in a different section of the plan from the first quoted passage, we must read the plan, like any other contract, as a whole, giving effect to every provision thereof. See Grider v. Transamerica Occidental Life Ins. Co., 979 F.2d 209 (5th Cir.1992) (table), manuscript opinion at 6-7 (citing Ross v. Western Fidelity Ins. Co., 872 F.2d 665, 668 (5th Cir.), opinion clarified on reh'g, 881 F.2d 142 (5th Cir.1989); D.E.W., Inc. v. Laborers' Int'l Union, 957 F.2d 196, 200 (5th Cir. 1989).

v.Blue Cross & Blue Shield of Oregon[9] the insurance contract defined "medically necessary" as treatment that rendered[.][10]

> [i]s appropriate and consistent with the diagnosis and which in accordance with accepted medical standards in the State of Oregon could not have been omitted without adversely affecting the patient's condition or the quality of medical care

Under that definition, the court held that the contract did not cover the insured's "Gerson therapy" or "immuno-augmentive therapy", two unorthodox cancer treatments. The court noted that the treatments had "not been approved by the appropriate government agencies" and were "not in accordance with accepted medical standards.[11] Accordingly, it concluded that the cancer

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9 *92 Or.App. 259, 758 P.2d 382 (1988).*

10 Id., 92 Or.App. at 261-62, 758 P.2d at 383. There also was a second contract involved in the Jacob case that contained a. nearly identical definition of "medically necessary". See id.

11 See Burzynski v. Aetna Life Ins. Co., 967 F.2d 1063, 1064 (5th Cir.1992), modified on reh'g, In re Burzynski, 989 F.2d 733 (5th Cir.1993), noting the opposition of various professional groups to antineoplastons therapy. See also 2 Rec. 398, 400 (Pl.'s Mot. Summ. J. & Rep. Def's Mot. Summ. J., Ex. R) , noting opposition of FDA and American Cancer Society.

treatments were not covered under the contract and upheld the trial court's summary judgment for the insurer.

We find the Jacob court's reasoning persuasive and its conclusion sound. Dr. Burzynski's antineoplastons treatment had not been approved by the FDA, nor by the Texas Department of Health, and was not in accordance with accepted medical standards.[12] Accordingly, the treatments were not "medically necessary" as the Plan defines that term. We uphold the district court's summary judgment for the Fund on the Fund's ERISA claim.

B. The Fund's Fraud Claim

The district court held that Dr. Burzynski defrauded the Fund by, inter alia, materially misrepresenting the legality of his antineoplastons treatment. After Judge McDonald's 1984 injunction, Dr. Burzynski was on notice that interstate use antineoplastons violated federal law. The portion of the Texas Health & Safety Code barring use or sale of non-FDA-approved drugs in Texas[13] put Dr. Burzynski on notice that intrastate distribution of antineoplastons was also illegal. Accordingly, Dr. Burzynski was on notice that both the intrastate and interstate applications of antineoplastons in

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Id. 92 Or.App. at 262, 758 P.2d at 383.

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See Tex. Health & Safety Code Ann. §431.114.

Huey Roberts's case were illegal. It is this illegality that the Fund charges Dr. Burzynski fraudulently withheld from it. Dr. Burzynski admitted that he never disclosed to the Fund that his antineoplastons A and B treatments were not approved by the FDA. The question, then, is whether the district court correctly ruled that this omission constituted fraud.

We begin with some basic principles. Texas law defines fraud as the "misrepresentation of a material f act with intention to induce action or inaction, reliance on the misrepresentation by a person who, as a result of such reliance, suffers injury".[14] A defendant's failure to disclose a material fact is fraudulent only if the defendant has a duty to disclose that fact.[15] A duty to speak can arise by operation of law or by agreement of the parties. In the absence of an agreement, there must be some special relationship between the parties, such as a fiduciary or confidential relationship,

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41 Tex. Jur. 3d Fraud and Deceit § 7 (1985) (footnotes omitted); see also Roberts v. United N.M. Bank, 14 F. 3d 1076, 1078 (5th Cir.1994).

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See, e. g. , Spoljaric v. Percival Tours, Inc. , 708 S.W.2d 432, 435 (Tex. 1986) ; Bernstein v. Portland Sav. & Loan Ass'n, 850 S.W.2d 694, 701 (Tex.App.-Corpus Christi 1991, writ denied).

before a duty to disclose arises.[16] The nondisclosing party must have had knowledge of the facts it withheld.[17] Even without a special relationship, there is always a duty to correct one's own prior false or misleading statement.[18] A speaker who makes a partial disclosure assumes a duty to tell the whole truth even when the speaker was under no duty to make the partial disclosure.[19]

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Stephanz v. Laird, 846 S.W.2d 895, 904 (Tex.App.-Houston [lst t.) 1991, writ denied). The relationship giving rise to a duty disclose may be either fiduciary or confidential in character; does not require a strict fiduciary relationship in all cases, See, e.g., Land v. Lee, 777 S.W.2d 158, 164 (Tex.App.-Dallas 1989 writ) (relationship of "trust or confidence") ; Southwestern Indem. Co. v. Cimarron Ins. Co., 334 S.W.2d 831, 833 (Tex.Civ.App.-Waco 1960) (same), rev'd on other grounds, 161 Tex. 516, 344 S.W.2d 442 (1961).

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HTM Restaurants, Inc. v. Goldman, Sachs & Co., 797 S.W.2d 326, 329 (Tex.App.-Houston [14th Dist.] 1990, writ denied).

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See, e.g., Ralston Purina Co. v. McKendrick., 850 S.W.2d 629, 635 (Tex.App.-San Antonio 1993, writ denied); Tempo Tamers, Inc. v. Crow-Houston Four, Ltd., 715 S.W.2d 658, 669 (Tex.App.-Dallas 1986, writ ref'd n.r.e.).

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Boggan v. Data Sys. Network Corp., 969 F.2d 149, 154 & n. 6 (5th Cir. 1992) ; Southeastern Fin. Corp. v. United Merchants & Mfrs., Inc., 701 F.2d 565, 566-67 (5th Cir. 1983); International Sec. Life Ins. Co. v. Finck, 475 S.W.2d 363, 370 (Tex.Civ.App.-Amarillo 1971), aff'd in part, rev'd in part on other grounds,. 496 S.W.2d 544 (Tex.1973).

1. Knowledge

Several of Dr. Burzynski's arguments challenge the district court's finding that he knew his antineoplastons treatment was illegal. He asserts that (1) Judge McDonald's injunction authorized the use of antineoplastons in Texas; (2) intrastate distribution of antineoplastons is authorized by the Texas Medical Practice Act; (3) he cannot be held to have known that antineoplastons were illegal because no Texas court has ever so decreed; and (4) the district court applied the wrong standard of scienter to the Fund's fraud claim. Because Dr. Burzynski's latter two challenges verge on the frivolous, we will discuss only the first two.

Dr. Burzynski acknowledges that Judge McDonald's 1984 injunction barred him from interstate distribution of the drug. He argues, however, that Judge McDonald authorized him to distribute antineoplastons in Texas. As did the district court, we find this argument unpersuasive. Judge McDonald limited the injunction to barring interstate distribution. Although the injunction did not forbid intrastate distribution, neither did it excuse Dr. Burzynski from compliance with state laws governing intrastate distribution of antineoplastons. The injunction simply is silent on the legality of intrastate distribution.

Dr. Burzynski next asserts that, even if § 431.114 of the Texas Health & Safety Code bars intrastate distribution of antineoplastons, that bar is superseded by § 5.09 of the Texas

Medical Practices Act ("TMPA"),[20] which provides:

> A physician licensed to practice medicine under this Act may supply patients with any drugs, or clinical supplies as are necessary to meet the patient's immediate needs. This subsection does not permit the physician to operate a retail pharmacy without first complying with the Texas Pharmacy Act ....

Dr. Burzynski argues-and a state administrative law judge recently agreed[21]-that the reference to "any drug" in the quoted text includes illegal drugs prohibited by the Texas Health & Safety Code. On our de novo review of state law, we follow the district court in rejecting this interpretation of the TNMA. Read as at whole, TMPA § 5.09 plainly is intended to authorize physicians to dispense drugs when urgent necessity precludes resort to a pharmacy. It does not clearly authorize anyone to dispense illegal drugs. We must road TMPA S 5.09 in harmony with Health & Safety Code § 431.114.[22]

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Tex.Rev.Civ.Stat.Ann. art. 4495b.

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See In re Burzynski, no. 503-92-529 (Texas State Office of Administrative Hearings, Mar. 10, 1994). The state ALJ's ruling was issued after this case was orally argued in this Court.

22

See Tex.Gov't Code Ann. § 311.026; Louisiana Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 370, 106 S.Ct. 1890, 1899, 90 L.Ed.2d 369 (1986).

Reading the statutes together, we cannot conclude that TMPA § 5.09 authorizes Dr. Burzynski to do anything forbidden by Health & Safety Code § 431.114.

2. Duty to Disclose

Two things are clear. The antineoplastons treatments administered to Huey Roberts in Texas and in Oregon were illegal, and Dr. Burzynski knew or should have known it. To uphold the district court's judgment on the Fund's claim of fraud, we must additionally decide that Dr. Burzynski had a duty to disclose to the Fund the illegality of the antineoplastons treatments. For three reasons, we conclude that he did.

First, Dr. Burzynski had a confidential relationship with the Fund. A confidential relationship includes "every form of relation between parties wherein confidence is reposed by one in another, and he relies and acts upon the representations of the other and is guilty of no derelictions on his own part".[23] It is an equitable concept that includes informal relationships outside the customary examples of partnerships, attorney/client relations, or familial

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Peckham v. Johnson, 98 S.W.2d 408, 416 (Tex.Civ.App.-Fort Worth 1936), aff'd, 132 Tex. 148, 120 S.W.2d 786 (1938) (quoted in Boggan, 969 F.2d at 154 n. 5). See also Thompson v. Vinson & Elkins, 859 S.W.2d 617, 624 (Tex.App.-Houston [1st Dist.] 1993,writ denied); Thames v. Johnson, 614 S.W.2d 612, 614 (Tex.Civ.App.-Texarkana 1981, no writ).

relations.[24] The Fund customarily relied, and was equitably entitled to rely, on Dr. Burzynski's representations as to the legality of his treatment.[25] Obviously, Dr. Burzynski had superior knowledge concerning the legality of his treatment, and knew that the Fund would have acted differently had it been aware that antineoplastons therapy was illegal. In such circumstances, Dr. Burzynski's duty to disclose is clear.[26] Dr. Burzynski's failure to disclose the illegality of antineoplastons treatment breached his confidential relationship with the Fund and gave rise to a claim of fraud in the Fund's favor.

Second, Dr. Burzynski's partial disclosures to the Fund

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In re Monnig's Dep't Stores, Inc., 929 F.2d 197, 201 (5th Cir.1991); Hruska v. First State Bank 727 S.W.2d 732, 736 (Tex.App.-Houston [1st Dist.] 1987) (confidential relationships include "moral, social, or personal relationships") , aff 'd in part, rev'd in part on other grounds, 747 S.W.2d 783 (Tex. 1988).

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We do not address whether the Fund would have been entitled to rely on representations by Dr. Burzynski (other than those implicating the legality of antineoplastons treatment.

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See, e.g., Susanoil, Inc. v. Continental Oil Co., 519 S.W.2d 230, 236 (Tex.Civ.App.-San Antonio 1975, writ ref'd n.r.e.); Chandler v. Butler, 284 S.W.2d 388, 398 (Tex.Civ.App.-Texarkana 1955, no writ); (cf. Moore & Moore Drilling Co. v. White, 345 S.W.2d 550, 555-56 (Tex.Civ.App.-Dallas 1961, writ ref'd n.r.e.); accord Mann v. Adams Realty Co., 556 F.2d 288, 297 (5th Cir.1977) (applying Alabama law); American Nat'l Ins. Co. v. Murray, 383 F.2d 81, 86-87 (5th Cir.1967) (applying Mississippi law).

imposed a duty on him to make such additional disclosures as would remove the false or misleading character of his partial disclosures.[27]

The claims forms Dr. Burzynski submitted to the Fund represented that "chemotherapy" was being administered to Huey Roberts. Considering that many perfectly legal forms of chemotherapy are employed in fighting cancer, the omission of the f act that this was not ordinary chemotherapy, but an unapproved drug that could not be lawfully administered in Texas or Oregon, was misleading.[28]

Finally, at the risk of laboring the obvious, Dr. Burzynski is a practicing physician, a trained professional licensed by the State of Texas. The practice of medicine in Texas is a privilege, not a right.[29] Among the prices the State exacts for the exercise of that privilege is that physicians hold themselves to a standard of ethical

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See supr notes 18-19 and accompanying text.

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Dr. Burzynski's brief argues that the abbreviation "ANPA" on the claims forms submitted to the Fund should be understood as a direct disclosure that he had been administering antineoplastons to Huey Roberts. The full description of service Dr. Burzynski entered in the claim forms reads: "High Dose ANPA chemotherapy IV drip". Try as we might, we are unable to read those words to make a sufficient disclosure that Dr. Burzynski sought reimbursement for the knowing illegal use (of an unapproved drug, not ordinary "chemotherapy".

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Tex.Rev.Civ.Stat.Ann. art. 4495b 5 1.02(l).

conduct befitting their position. For example, physicians may find themselves subject to disciplinary action for

> unprofessional or dishonorable conduct that is likely to deceive or defraud the public or injure the public .... including but not limited to the following acts:
>
> (A) committing any act that is in violation of the laws of the State of Texas if the act is connected with the physician's practice of medicine.[30]

This is a salutary policy. We would damage it if we held that Dr. Burzynski was free to defraud a health insurer by obtaining reimbursement for illegally administered treatment. In conjunction with the other factors just mentioned, Dr. Burzynski's ethical responsibility as a physician supports the conclusion that he had a duty to disclose the illegality of the antineoplastons treatment.

Because we conclude that Dr. Burzynski failed to disclose the illegality of his antineoplastons treatment to the Fund when he had a duty to do so, we uphold the district court's judgment on the Fund's claim of fraud. We need not address the other grounds offered by the plaintiff for affirming the district court, such as Dr. Burzynski's alleged misrepresentations as to the location of the treatment.

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Id. S 3.08(4).

III.

We close by echoing the concluding thoughts of the late Judge Alvin Rubin in one of the previous lawsuits involving Dr. Burzynski.[31] Cancer victims, such as Huey Roberts, often are understandably eager to pursue any course of treatment, whatever its cost or efficacy, that offers the faintest hope of preserving life. Their plight commands sympathy, but also attracts opportunists. The State of Texas and the Federal Food and Drug Administration have stepped in to protect cancer patients from those who would prey on their vulnerability. While we do not impute evil motives to Dr. Burzynski, neither can we conclude that he is beyond the laws written to protect his patients. When he oversteps their bounds, the resulting costs are his to bear.

The district court's judgment is AFFIRMED.

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See United States v. Burzynski Cancer Research Inst., 819 F.2d 1301, 1315 (5th Cir.), reh'g denied, 829 F.2d 1124 (5th Cir.1987), cert. denied, 484 U.S. 1065, 108 S.Ct. 1026, 98 L.Ed.2d 990 (1988).

EXHIBIT "C"

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

TRUSTEES OF THE	§	
NORTHWEST LAUNDRY AND	§	
DRY CLEANERS HEALTH	§	
& WELFARE TRUST FUND	§	CIVIL ACTION NO. H-91-347
	§	
VS.	§	
	§	JURY TRIAL REQUESTED
STANISLAW R. BURZYNSKI	§	

MEMORANDUM AND ORDER

Defendant has filed a Motion for reconsideration, reargument and to alter and amend judgment. Defendant claims that this Court erred in granting summary judgment because the Court did not find that Defendant had a dutv to disclose the illegality of his treatment and because the Court used an incorrect standard of scienter. After another review of the pleadings, motions and exhibits filed in this case, the Court is of the opinion that its order of October 13, 1992 was correct.

In their motions for summary judgment, both Plaintiff and Defendant contended that the sole issue for the Court to decide was the legality of Defendant's treatment. The Court did decide that issue, but went further and specifically addressed Plaintiff's claim of fraud. The argument that the Court's failure to find a duty to disclose on the part of Defendant is without merit. This Court, based on the claim for,-,is, found that Defendant had materially and affirmatively misrepresented the location of the insured's treatment. The argument that the court used the incorrect standard of scienter is also without merit. This Courtis opinion traces Defendant's knowledge of the illegality of his treatment from the clear meaning of the Texas Food, Drug and Cosmetic Act to the opinion by Judge McDonald to the opinion letter of the Texas Department 'of Health. Willful blindness is not a defense to knowledge and for Defendant to claim that he

did not know that his treatment was illegal in Texas given the Texas statute and all the documents before the Court is ludicrous. It is therefore

ORDERED that Defendant's notion for reconsideration, reargument and to alter or amend judgment (#24) is DENIED.

Signed this 10th day of December, 1992 at Houston, Texas.

Norman W. BLACK
CHIEF JUDGE

EXHIBIT "D"

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

TRUSTEES OF THE NORTHWEST LAUNDRY AND DRY CLEANERS HEALTH & WELFARE TRUST FUND	§	CIVIL ACTION NO. H-91-347
VS.	§	JURY TRIAL REQUESTED
STANISLAW R. BURZYNSKI	§	

MEMORANDUM AND ORDER

Pending before the Court are cross motions for summary judgment. Defendant is requesting summary judgment as to all claims. Plaintiffs are seeking summary judgment only as to its fraud and ERISA claims. After consideration of the motions, memoranda of law in support of the motions, and exhibits, the Court is of the opinion that there are no genuine issues of material fact and, for the reasons discussed below, Plaintiff' motion for summary judgment on its fraud and ERISA claims should be granted. Defendants' motion for summary judgment on the RICO claim should be granted but denied as to all other allegations.

Plaintiffs, trustee of an ERISA qualified health plan brought suit against Defendant, a physician for fraud, RICO

violations[1] and ERISA violations. Plaintiffs claim that Defendant sold, used and administered an experimental drug, antineoplastons, in violation of Texas law to an insured of Plaintiffs' health plan.

According to Plaintiffs, the insured was initially treated in Texas and then received the antineoplastons in Oregon where the insured resided. Payment of approximately $97,000 were made on behalf of the insured to Defendant. Plaintiffs claim that after the payments were made they discovered that Defendant's treatment was illegal under Texas law. Due to the illegality of the treatment and Defendants' representations that the treatment was standard and wholly sanctioned under Texas law, Plaintiffs claim they are entitled to reimbursement of the $97,000.

Summary Judgment is appropriate if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. The United States Supreme Court has interpreted this rule to mandate the entry of summary judgment after an adequate time for discovery against a party who fails to make a showing sufficient to establish the existence of an essential element to that party's case, and on

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Plaintiff has not sought summary judgment on the RICO claim and has presented no evidence of two or more acts of racketeering activity that is needed to support the claim.

which that party will bear the burden of proof at trial. Celotex Corp. v. Catrett 477 U.S. 317 (1986).

To establish a fraud claim for fraud under Texas law a plaintiff must show that 1:) a material misrepresentation was made; (2 the representation was false; (3 the representation was made with knowledge of its falsity; 40 the representation was made to induce the other party to act; (5 the other party relied on the representation; and 6) the other party was injured due to its reliance on the representation Haney v. Purcell., Inc. 796 S.W. 2d 782 (Tex.App.--Houston [1st Dist.] 1990, writ denied).

Plaintiffs contend that Defendant misrepresented the legitimacy of his treatment and misrepresented the location of treatment. Plaintiffs further contend that Defendant knew his treatment was prohibited by Texas law, but canceled this fact from Plaintiffs, resulting in Plaintiffs' reliance, to its detriment, on Defendant's representations.

Texas' Food Drug and Cosmetic Act provides that: "no person shall sell, deliver, offer for sale, hold for sale or give away any new drug[2] unless an application has been approved under 21

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Section 431.002 of the Texas Health and Safety Code defines a new drug as: "(A) any drug, except a new animal drug, the composition of which is such that such drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe for use under the conditions prescribed, recommended or suggested in the labeling thereof; or (2) any drug, except a new animal drug, the composition of which is such

U.S.C. 355, the Federal Food, Drug and Cosmetic Act, or unless the drug has been tested and found to be safe and effective and prior to selling or offering the drug for sale the state health commissioner has an application for approval on file. Tex. Health and Safety Code Ann. Section 431.114 (formerly Tex Rev. Civ. Stat. Ann. art 4476-5 section 16).

The uncontested facts in this case show that Defendant's experimental drug, antineoplastons, was a "new drug" within the meaning of the Texas statute, that it was not approved under the Federal Food Drug and Cosmetic Act and that Defendant, at the time of the insured's treatment had not filed an application for approval with the Texas health commissioner. Defendant's sale and delivery of antineoplastons to Plaintiffs' insured was therefore a violation of Texas law.

Defendant's argument that his antineoplaston drugs and treatment are legal is based on the Texas Medical Practices Act, Tex. Rev Civ. Stat. Ann. art 4496b Section 5.09, which allows a licensed physician to "supply patients with any drugs, remedies, or

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that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been use to a material extent or for a material time under such conditions.

clinical supplies as are necessary to meet the patients' immediate." claiming that the statute, which uses the words "any drugs" is clear and unequivocal, Defendant argues that because he is a physician he can prescribe any drug, regardless of the underlying legality of the drug.

This argument that the Texas Medical Practices Act in effect negates the provisions of the Texas Food Drug and Cosmetics Act is without merit. When state statutes apparently conflict, it is not within the province of the Court to determine which statute controls. On the contrary, it is within the province of the judiciary, if at all possible, to harmonize seemingly conflicting statutes. Louisiana Public Service Com'n v. F.C.C., 476 U.S. 355, 370 (1986).

The Texas Food, Drug and Cosmetic Act and the Texas Medical Practices Act are easily reconciled. If the word "any drugs' in the Texas Medical Practices Act really meant any drug, regardless of approval by the FDA and regardless of whether the drug was classified as a controlled substance, physicians would be able to create and market their own experimental drugs without any testing and without any government oversight. Physicians would also have complete and unlimited access and authority over controlled substances, a position that state and federal legislators have continually denied. Surely the Texas legislature did not intend with the Texas Medical Practices Act to excuse physicians

from compliance with Texas' food and drug statutes. If the Texas legislature had meant to take such a aberrant step, it would obviously have stated its intent more clearly. Because this Court cannot conceive that the words "any drugs" in the Texas Medical Practices Act are to be read that strictly, this Court finds that the words "any drugs" in the Texas Medical Practices Act refers to any drugs that meet the approval standards of either the Federal Food, Drug and Cosmetic Act or the Texas Food, Drug and Cosmetic Act.

Defendant also relies on an opinion written by Judge McDonald of the Southern District of Texas in United States of America v. Burzynski Cancer Research Institute, et al, cause number H-83-2069, as support for his claim that his drugs and treatment are legal in Texas.

The McDonald opinion in the case cited by Defendant resulted in a permanent injunction against Defendant, prohibiting him from "introducing or delivering for introduction into interest commerce" any component of his experimental antineoplaston drug. The order also, however, provided that:

> [n]othing contained herein shall be construed as restraining, enjoining or in any way prohibiting the Defendants' manufacture, processing, packing, holding, promotion, labeling, sale or distribution of the antineoplaston A10 or of any similar article however designated when that manufacture, processing, packing, holding, promotion, labeling, sale or distribution is undertaken strictly and

wholly intrastate.

Defendant erroneously relies on this provision as an affirmative endorsement of his treatment within the state of Texas. Judge McDonald's order does not, as Defendant claims, establish the legality of Defendant's treatment within the state of Texas' the order merely declines to rule on any intrastate activity by Defendant. Because Judge McDonald's opinion does not establish the legality of Defendant's drug or treatment and because the Texas Food, Drug and Cosmetic Act has not been complied with, Defendant's sale, delivery or offer to sell antineoplastons are prohibited until such time as Defendant's application has been approved under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §355, or until the drug has been tested and found to be safe and effective upon application to the Texas state health commissioner.

As to Plaintiffs' fraud claim, Plaintiffs have established that Defendant, both in the manner that he presented his claim forms to Plaintiffs on behalf of the insured and in his correspondence with Plaintiffs, failed to disclose the questionable legitimacy of his treatment. Defendant never disclosed to Plaintiffs that his drug treatment was not approved by the FDA nor that his treatment was anything other than standard "chemotherapy."

Defendant also materially misrepresented where treatment

was administered, presumably to avoid the repercussions of Judge McDonald's order prohibiting Defendant's sale or delivery of antineoplastons in interstate commerce. On all the claim forms, in the box entitled "Name and Address of Facility where services Rendered (if other than home or office)," Defendant responded "N/A". Defendant knew that his treatment was initially administered to the insured in Houston, Texas, at his clinic, but Defendant also knew that after the initial treatments, his antineoplaston drugs were sent to the insured in Oregon, clearly violating Judge McDonald's injunction prohibiting the sale or delivery of antineoplastons in interstate commerce. The response on the claim forms of "N/A," given Defendant's knowledge of the treatment locations, was fraudulent.

There is ample evidence provided by both Plaintiffs and Defendant that Defendant knew or should have known that his antineoplaston treatment was in violation of Texas statute. Defendant has been involved in countless lawsuits over his antineoplaston treatment. While he is correct in stating that no court has determined that his treatment is illegal under Texas law, the Texas Food, Drug and Cosmetic Act speaks for itself. In addition, Defendant was on notice from the Texas Department of Health that they considered his treatment to be in violation of the statute. Given the clear language of the Texas Food, Drug and Cosmetic Act, as addressed above, the Court finds that

Defendant has not complied with the statutory requirements and that he knew or should have known that his treatment was in violation of Texas law.

There is also sufficient evidence, based on the misleading way in which Defendant filed the claim forms, that he intended to induce Plaintiffs into paying for the treatment without further inquiry into the legitimacy of the treatment. The payment of approximately $97,000.00 to Defendant on behalf of the insured evidences Plaintiffs' reliance and resulting injury.

Because the Court finds that Defendant has not complied with Texas law regarding new drugs, and because Defendant misrepresented the legitimacy of his treatment, Plaintiffs are entitled to reimbursement of approximately $97,000.00.

Since there is no evidence to support Plaintiffs' RICO claim, Defendant's motion for summary judgment as to that claim should be granted. It is therefore

ORDERED that Defendant's notion for summary judgment is GRANTED only as to the RICO claim. Defendant's motion for summary judgment on the fraud and ERISA claims (#14) is DENIED. It is further

ORDERED that Plaintiffs' Motion for Summary Judgment on its fraud and ERISA claims (#20) is GRANTED. It is further

ORDERED that Plaintiffs recover from Defendant the

principal sum of $96,963.56 together with prejudgment interest at the r ate of 3.137% per annum. It is further

ORDERED that Defendant pay post-judgment interest at the rate of 3.137% per annum on this judgment from the date of judgment until paid. It is further

ORDERED that Defendant pay Plaintiffs' reasonable attorney's fees. Plaintiffs' shall submit an affidavit with supporting documentation showing the amount of attorneys, fees and costs incurred.

Signed this 13th day of October, 1992 at Houston, Texas.

Norman W. Black
Chief Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

TRUSTEES OF THE	§	
NORTHWEST LAUNDRY AND	§	
DRY CLEANERS HEALTH	§	
& WELFARE TRUST FUND	§	CIVIL ACTION NO. H-91-347
	§	
VS.	§	
	§	JURY TRIAL REQUESTED
STANISLAW R. BURZYNSKI	§	

FINAL JUDGMENT

This Court having GRANTED Plaintiff's motion for summary judgment on the fraud and ERISA claims, and Defendant's notion for summary judgment only on the RICO claim, this action is hereby DISMISSED with prejudice. The Court hereby enters

JUDGMENT that Plaintiffs have and recover from Defendant the principal sum of $96,963.56 plus prejudgment interest at the rate of 3.137% per annum, post-judgment interest at a rate of 3.137% per annum from the date of judgment until paid, and Plaintiffs' reasonable attorney's fees.

This is a FINAL JUDGMENT.

Signed this 13th day of October, 1992 at Houston, Texas.

NORMAN W. BLACK
CHIEF JUDGE

EXHIBIT "E"

DOCKET NO. 503-92-529

IN THE MATTER OF	§	BEFORE THE
	§	
THE COMPLAINT AGAINST	§	STATE OFFICE OF
STANISLAW R. BURZYNSKI,	§	
M.D., PH.D.	§	ADMINISTRATIVE HEARINGS

PROPOSAL FOR DECISION

The staff of the Texas State Board of Medical Examiners initiated this action seeking disciplinary action against the license of a physician for administering to patients a new drug which was not approved by the authorities, for charging a fee for the drug administered, and for advertising that the drug affected human cancers. The Respondent contended that his treatment of patients was not outside the law, that he was not prohibited from charging a fee for his treatments, and that the proposed prohibition against his advertising is too broad. This proposal finds that the Respondent has violated the Texas Food, Drug and Cosmetic Act's prohibition against false advertising and recommends that the Board issue a cease and desist order directing the Respondent to bring his advertising into compliance with the Texas Food, Drug and Cosmetic Act.

1.Procedural History

The staff of the Texas State Board of Medical Examiners (the Board) initially notified Stanislaw R. Burzynski, M.D., Ph.D.,

(Respondent), by letter dated July 28, 1986, that it had received complaints regarding the Respondent's treatment of cancer patients. The letter set a date for an informal hearing and offered the Respondent an opportunity to present evidence to rebut the charges. Following the informal hearing, the matter was apparently held in abeyance pending a review by Board-selected oncologists of patients' charts provided by the Respondent. Following the receipt of communications, in May 1988, from the Texas Department of Health, the matter was apparently revived. Prehearing conferences were held on October 21 and 24, 1988, and on December 4, 1990, to address issues to be considered at hearing. On or about October 26, 1992, the matter was referred to the State Office of Administrative Hearings, a document entitled Second Amended Complaint was filed, and the matter was set for a hearing on the merits on December 14, 1991 Pa the request of the parties, on November 19, 1992, the hearing on the merits was continued to a date to be selected by the parties and a preheating conference was set for December 16, 1992. On December 1, 1991 the first of approximately 70 petitions to intervene and motions to be admitted as a party in the case was filed by a patient of the Respondent. The petitions alleged that intervention was sought on the grounds that the Intervenors suffer from a life threatening medical condition, that the State's interference with the Intervenors' treatment constituted an invasion of the Intervenors' constitutional right to privacy and the

Intervenor's constitutional right to life, and that the State's withdrawal of the treatment without granting the Intervenor a hearing would constitute a denial of due process. The preheating conference, scheduled for December 16, 1992, was continued to January 4, 1993, to consider the petitions to intervene.
Following the preheating conference and the receipt of briefs on January 22, 1993, the Administrative Law Judge, by order, dated March It 1993, denied the petitions to intervene and the motions for party status.

The hearing on the merits commenced on May 24, 1993, in the Clements Building, 300 West 15th Street, Austin, Texas. Because of public interest in the proceeding, the hearing was moved to the Sam Houston Building, 14th Street at Brazos, Austin, Texas. The hearing continued on May 25, 1993, in the Clements Building. After the taking of evidence, the hearing was recessed to August 12, 1993, for the receipt of additional documentary evidence, proposed findings of fact, conclusions of law and briefs from the parties. The hearing was closed on August 12, 1993. The Board was represented by Dewey E. Helmcamp, III, Assistant Attorney General. The Respondent appeared and was represented by Richard A. Jaffe, Attorney.

II. Jurisdiction and Notice

The Texas State Board of Medical Examiners has jurisdiction over this matter pursuant to TEX. REV. CIV. STAT. ANN. art. 4495b. The State Office of Administrative Hearings has jurisdiction over matters related to the hearing in this proceeding, including the authority to issue a proposal for decision with proposed findings of fact and conclusions of law pursuant to TEX. REV. CIV. STAT. ANN. art. 6252-13f.

The parties stipulated "[t]hat all jurisdictional prerequisites of the Texas Administrative Procedure and Texas Register Act (APTRA) have been met and satisfied, including the notice of complaint and investigatory letter (section 18c, APTRA), and notice of the time and place of the hearing before the State Office of Administrative Hearings."

III. Applicable Statutes and Rules

The applicable statutes are set forth in the appendices.

Appendix A contains applicable portions of the Texas Food, Drug and Cosmetic Act which was effective between September 1, 1989, and the date of filing the Second Amended Complaint, August 14, 1992.

Appendix B contains applicable portions of the Texas Food, Drug and Cosmetic Act which was effective between September 1, 1985, and August 31, 1989.

Appendix C contains applicable portions of the Texas Food, Drug and Cosmetic Act which was effective between the date of the first alleged offense and August 31, 1985

Appendix D contains applicable portions of the Texas Intractable Pain Treatment Act.

Appendix E contains applicable portions of the Texas Dangerous Drug Act.

Appendix F contains applicable portions of the Texas Medical Practice Act.

Appendix G contains applicable portions of 21 U.S.C. Chapter 9, Federal Food, Drug and Cosmetic Act.

Appendix H contains applicable portions of 21 U.S.C. Chapter 11, Manufacture of Narcotic Drugs.

Appendix I contains applicable portions of 21 U.S.C. Chapter 13, Drug Abuse Prevention and Control.

Appendix J contains applicable rules of the Texas State Board of Medical Examiners.

Appendix K contains applicable portions of 21 Code of Federal Register, Chapter 1.

IV. Positions of the Parties

A. Charges by the Board

The charges against the Respondent are made in four counts some with several part.

1. Count I alleges in Parts A, and B that the Respondent administered antineoplastons to his patients without having approval from the Federal Food and Drug Administration (FDA) and without having a letter of approval or approvability on file with the Texas Department of Health (TDH). Each part addresses a specific period of time during which a particular version of the Texas Food, Drug and Cosmetic Art (TFDCA) us in effect.

Count I alleges in Part C that the Respondent administered antineoplastons to his patients before September 1, 1985, without having the approval of TDH.

Count I alleges in Part D that the Respondent administered antineoplaston A-10 to patients during a period of time when the FDA had placed a "clinical hold" on the Respondent's study of antineoplaston A-10.

2. Count II specifies 40 individual patients and alleges that the Respondent between October 9, 1975, and April 7, 1987, administered antineoplastons, to the individual patients for various forms of cancer. The Respondent's treatments are alleged to have been in violation of the TFDCA.

3. Count III alleges that from September 1, 1985, until August 14, 1992, the Respondent disseminated advertising which represented that antineoplastons affect cancer and that the advertising was false.

4. Count IV alleges that from September 1, 1985, until August 14, 1992, the Respondent charged fees for antineoplastons in

violation of federal regulations and that the fees charged constituted persistent and flagrant overcharging.

B. Stipulations

The parties stipulated to the following:

1. That Respondent, Stanislaw R. Burzynski, M.D., PhD., was issued Texas Medical License Number D-9377 by the Texas State Board of Medical Examiners and that the license was in force at all times pertinent to the allegations against the Respondent.

2. That all jurisdictional prerequisites of the Texas Administrative Procedures and Texas Register Act (APTRA) have been met.

3. That the Board has jurisdiction over the subject matter of the hearing and, in conjunction with the State Office of Administrative Hearings, has authority and jurisdiction to hear and resolve the allegations against the Respondent.

4. That, as alleged in the Board's Second Amended Complaint, Respondent has administered antineoplastons to his patients during the times specified in Count IA, IB, IC, and ID. That, as of the date of hearing, no formulation of antineoplastons has been approved for commercial, interstate marketing by the Federal Food and Drug Administration pursuant to Section 505 (Appendix H) of the Federal Act and that no letter of approval or approvability issued by the Federal Food and Drug Administration is on file with

the Commissioner of the Department of Health.

5. That, as alleged in Count IL]Respondent treated the patients listed, a through nn, with Antineoplastons.

6. That, during the times alleged in Count III, the Respondent disseminated certain materials which were produced by the Respondent and attached as exhibits to the deposition of the]Respondent taken on April 27, 1992.

C. Respondent's Defenses

The Respondent denied:

1. That any of his actions, including his administration of antineoplastons to his patients, at any time pertinent to the allegations was a violation of the Medical Practice Act or of the TFDCA in any of its forms.

2. That the writings mentioned in Count III are subject to regulation under §431.183(a)(2) of the Health and Safety Code and asserted that the writings were true.

3. That his treatment of patients during the time specified in Count IV was subject to regulation under 21 CFR §312.7(a)(d).

4. That any of his actions were grounds for cancellation, revocation or suspension of his license, or constituted grounds for issuance of an order imposing other

means of discipline upon him, or warranted imposition of any sanction against him.

The Respondent raised six affirmative defenses:

1. That the entire proceeding is barred by the doctrine of estoppel and waiver.

2. That the Respondent's alleged actions are sanctioned under §5.09 of the Medical Practice Act.

3. That the Respondent's treatment of patients is sanctioned by Section 3 of the Texas Intractable Pain Treatment Act and that insofar as the proceeding is based upon the Respondent's use of antineoplastons on patients, the proceeding is barred by §5 of the Texas Intractable Pain Treatment Act.

4. That the Board's application of §431.114 of the TFDCA violates the federal and Texas state constitutional right of privacy and the right to life of the Respondent's terminally ill patients.

5. That §431.114 of the TFDCA has no application to terminally ill patient.

That Count III violates the Respondent's constitutionally protected right to free speech insofar as it seeks to impose sanctions upon the Respondent based upon his statements regarding his opinions, ideas, and findings

regarding his discoveries, and that §431.183(a)(2) of the Health and Safety Code is unconstitutional insofar as it purports to prohibit pure speech and/or unreasonably restrict the dissemination of truthful commercial speech.

V. Evidence and Analysis

Historical Perspective

The Respondent graduated from the Medical Academy, Lublin, Poland, in 1968. He then received a Ph.D. in biochemistry in 1968. In his research at the Medical Academy, the Respondent discovered certain peptides in human blood which were deficient in the blood of cancer patients. The Respondent isolated the peptides. After testing the peptides the Respondent concluded that several of the peptides inhibited cancer cell growth without damaging normal cells. The Respondent labeled the peptides which he believed to inhibit the growth of cancer cells "antineoplastons." In 1970 the Respondent came to the United States and began mark at Baylor College of Medicine where he continued his research in the area of antineoplastons. In 1973, the]Respondent was licensed as a physician by the Texas State Board of Medical Examiners. In 1977 the Respondent left the employ of Baylor College of Medicine and opened his own laboratory. The laboratory later

was named Burzynski Research Institute (BRI). Currently the Respondent practices as a solo practitioner and is the president of BRI. (Tran. 147-149).

The complaint upon which this case is based was filed with the Board of Medical Examiners by the Texas Department of Health after several unspecified persons appeared on the Sally Jessy Raphael television show in 1988 and championed the Respondent's cancer treatment. (Tran. 49-50, 82-83). A letter written by the Texas Department of Health to the Respondent, dated May 2, 1988, notified the Respondent that his use of antineoplaston therapy to treat various types of cancer constituted a violation of Section 18 of the TFDCA. (Tran. 27, Ex. 8). The letter was a warning letter to the Respondent stating that the Department believed him to be in violation of the law. (Tran. 95-96). A copy of the letter to the Respondent was forwarded to the Board. (Tran. 47, 97).

B. Evidence and Analysis Related to Charge I

The evidence and analysis of Charges IA, IB, and IC shall be addressed beginning with the charge earlier in time and then moving forward in time. As a result, those charges will be addressed in the order, IC, IB, then IA.

1. Charge IC

Part C of Count I alleges that the Respondent prior to and until September 1, 1985, administered antineoplastons designated A, A-2, A-3, A-5, A-10, AS2-5, and AS-5 to his patients, without having the approval of TDH, in violation of Section 16(a)(1) of the TFDCA.

a. The Staffs evidence related to Charge IC

The Respondent stipulated that he administered antineoplastons to his patients during the time specified in Count IC. (Ex. 15).

A copy of TEX. REV. CIV. STAT. ANN. art. 4476-5 §16 (Appendix C) was offered into evidence. Section 16 was in effect from the date the Respondent departed the employ of Baylor College of Medicine until August 31, 1985.

The term "new drug" referenced in Section 16 is defined in the "federal Act" at 21 U.S.C. §321(p) which is included in Appendix G.

Dennis E. Baker is Director of the Division of Food and Drugs for the Texas Department of Health. He holds a Bachelor's Degree in Biology and a Master's Degree in Public Administration. Mr. Baker was the Board's sole witness. He testified that the Respondent contacted TDH in late 1977 or

early 1978 regarding obtaining an Investigational New Drug Application but in a conversation with James 0. Allen, Jr., the Drug Branch Chief, in January 1978, the Respondent advised Mr. Allen that he had decided not to pursue the matter. (Tran. 28-29). Exhibit 9 contains a copy of the memo written by Mr. Allen after his conversation with the Respondent. It is dated January 28, 1977.

Exhibit 30, an Order filed May 24, 1983, and entered in Cause Number H-83-2069, United States of America v. Burzynski Cancer Research Institute, et al, in the United States District Court for the Southern District of Texas, Houston Division, recites in Finding of Fact No. (2) and Conclusion of Law No. 6, that antineoplastons A2, A3, A5, A10, and AS2-1 are "drugs' within the meaning of 21 U.S.C. §321(g) and "new drugs" within the meaning of 21 U.S.C. §321(p).

No evidence was admitted, either by document or by testimony, that antineoplastons A, AS2-5 or AS-5 are "drugs" or "new drugs" as defined in 21 U.S.C. §321(g) and (p).

b. The Respondent's evidence related to Charge IC

Dennis E. Baker testified that TDH did not take any action against the Respondent during the time Section 16 was in effect. (Tran. 47-48). Mr. Baker also testified that TDH was

aware of, followed, and maintained contact with the FDA regarding, the FDA's attempt to obtain an injunction against the Respondent in 1983. TDH did not attempt to intercede in the FDA action. (Tran. 50-51). TDH also did not, at any pertinent time, adopt any rules interpreting Section 16. (Tran 40, 91-92). Mr. Baker testified that he was aware that the FDA obtained an injunction preventing the Respondent from distributing antineoplastons in interstate commerce and was aware that the Federal Judge specifically stated in her Order that the Respondent was free to treat patients with antineoplastons within the State of Texas. (Tran. 51, 85-86). He did not know whether TDH had any opinion regarding whether the Respondent was in violation of Section 16 during the time which it was effective, nor was he aware of TDH taking action against any physician under Section 16. (Tran. 52). In 1977, Bob Henna was the Director of the Division of Food and Drugs, Texas Department of Health, and was Mr. Baker's immediate predecessor. In 1977, Hal Nelson was the General (Counsel for the Texas Department of Health. (Tran. 4142Y Dennis Baker testified that the Food and Drug Division of the Texas Department of Health is responsible for overseeing the enforcement of the provisions of the Texas Food, Drug and Cosmetic Act. (Tran. 23). The legal staff of

the Texas Department of Health answers questions related to the Department's governing legislation and gives advice, either orally or in writing, to persons who seek it. (Tran. 57-58).

The Respondent testified that in 1977 he had an offer to join the faculty at the University of Tennessee where he would have continued his research into antineoplastons. The Respondent, however, did not wish to leave Texas. He retained the law firm of Caldwell and Baggott to determine whether he could lawfully produce and use antineoplastons in his private practice as the treatment for his patients in the State of Texas. (Tran. 153-154). The Respondent testified by deposition that in 1977 he was visited by two employees of the Texas Department of Health who informed him that it was permissible for him to make and use antineoplastons and that there was no requirement that he make a filing with TDH. (Exhibit 16, pg. 27).

Exhibit 10 is a legal memorandum, dated February 8, 1977, prepared for G. Earnest Caldwell of the Caldwell and Baggott firm. The memo addressed the exception contained in Section 16 of the TFDCA regarding investigational use of new drugs then stated, "The problem with interpreting this exception is the fact that there is no Texas case law on this point, nor are there any Regulations issued by the

Commissioner of Health'. Additionally §§505(i) and 507(d) -. do not apply to our situation as there will be no interstate involvement." The memo relied upon information received in conversations with Bob Henna and Hal Nelson, of TDH, in which they opined that "...the Texas legislation does not direct itself toward a situation such a ours where the doctor prepares a medication which he administers to the patient directly himself and does not otherwise , sell or distribute the medication."

Exhibit 11 is a letter, dated June 21, 1977, from G. Earnest Caldwell of the Caldwell and Baggott firm to the Respondent. The letter states that the writer is of the opinion that the Respondent's preparation of antineoplastons, his use of them in the laboratory and his administration of antineoplastons to patient in the course of his medical practice was not governed by the TFDCA nor was it otherwise unlawful under Texas law. The letter further stated that such use within the State of Texas would not contravene federal law because it would not constitute interstate commerce. The letter recited that it relied upon oral advice from Hal Nelson and Bob Henna that the TFDCA was not applicable.

The Respondent testified that based upon the opinions received from his attorneys, he left Baylor College of

Medicine at the end of June 1977, opened his laboratory attached to his private practice in Houston, Texas, and proceeded to begin to use antineoplastons in the treatment of his patients rather than accept the offered tenured position and substantial research funding from the University of Tennessee. (Tran. 156).

The Respondent admitted that in 1983 the FDA sought and obtained an injunction which prohibited him from shipping antineoplastons outside the State of Texas unless the Respondent first obtained approval of the FDA. He testified that the Order issued by Federal Judge Gabrielle McDonald did specifically allow him to continue to produce and use antineoplastons on patients inside of Texas. (Tran. 157).

The Order issued by Judge McDonald (Exhibit 30) contains the following language: "Nothing contained herein shall be construed as restraining, enjoining or in any way prohibiting the Defendant's [Respondents] manufacture, processing, packing, holding, promotion, labeling, sale or distribution of the antineoplaston A1O or of any similar article however designated (provided articles are not falsely labeled or marked) when that manufacture, processing, packing, holding, promotion, labeling, sale or distribution is undertaken strictly and wholly intrastate."

c. Analysis of the evidence relating to Charge IC

The Board had the burden of proving by a preponderance of the evidence each denant of the allegations made against the Respondent !Die Respondent had the burden of proving by a preponderance of the evidence the elements of any affirmative defense raised. The Respondent raised an affirmative defense by asserting that the entire proceeding was barred by the doctrines of waiver and estoppel.

Under different circumstances the concept of estoppel would apply to Charge IC. Estoppel arises in the case where through the fault of one party another party is induced to change its position for the worse The party gaining the undue advantage is precluded from using that advantage against the injured party. In this case the Respondent relied, to his detriment, upon information received from the General Counsel of the Texas Department of Health and the Director of the Division of Food and Drug Texas Department of Health. However, estoppel does not work against the state in the exercise of its governmental powers. Sorsby v. State, 624 S.W2d 227 (Tex. Civ.App.- Houston [lst Dist] 1981, [no writl.

There is a concept akin to estoppel which does apply to the state. The mistake of law defense precludes prosecution when the state is the source of the actor's mistaken understanding of the law. This defense is found at TEX. PENAL CODE ANN. §8.03, which states, in part, "(b) It is an affirmative defense to prosecution that the actor reasonably believed the conduct charged did not constitute a crime

and that he acted in reasonable reliance upon: (1) an official statement of the law contained in a written order grant of permission by an administrative agency charged by lay, with responsibility for interpreting the law in question. . ." (emphasis added). While the Penal Code is not applicable, inasmuch as this case is not a criminal prosecution, the concept of the mistake of law defense, by analogy, is applicable.

In this case the Respondent's attorneys contacted the General Counsel for the Texas Department of Health and contacted the person responsible for the interpretation and enforcement of the provisions of the Texas Food, Drug and Cosmetic Act to determine whether the Respondent could lawfully produce antineoplastons and use them in the treatment of his patients in Texas. The attorneys got affirmative responses from both individuals. The Respondent turned down an offer which assured him the opportunity and funding for continued research in reliance upon the information received from TDH. The Respondent's actions in reliance upon the grant of permission from the administrative agency charged by law with the responsibility for interpreting the Texas Food, Drug and Cosmetic Act, were therefore not in violation of that Act.

Evidence was received of additional reasons for not finding Charge IC proven. During the period of time covered by all allegations, the Respondent, by his testimony, has been involved in research into the use of antineoplastons in the treatment of various

cancers. That use falls within the exception stated in Section 16(c). The TDH did not enact rules interpreting Section 16 and therefore did not provide the Respondent with guidance by that route. Further, during the period of time, the TDH was familiar with the Respondent's treatment of patients with antineoplastons. The TDH did not determine that the Respondent was in violation of Section 16 at the time nor did they attempt to take any action against the Respondent. Without rules interpreting Section 16 and without an adverse determination by the TDH, the evidence indicates that the Respondent's treatment of his patients with antineoplastons while Section 16 was in effect fell within the exception found at Section 16(c). The Staff failed to prove Charge IC by a preponderance of the evidence.

2. Charge IB

Part B of Count I alleges that the Respondent from September 1, 1985, to September 1, 1989, administered antineoplastons, including those designated A, A-2, A-3, A-5, A-10, AS2-1, AS2-5, and AS-5, to his patients without having the approval of the FDA pursuant to 21 U.S.C. §505 and without having a letter of approval or approvability on file with the Commissioner of Health, TDH, in violation of Section 18(a) of the TFDCA.

a. Staffs evidence related to Charge IB

The Respondent stipulated that he administered antineoplastons to his patients during the time specified in Count IB. The Respondent also stipulated that no formulation of antineoplastons has been approved for commercial, interstate marketing by the FDA pursuant to Section 505 of the Federal Act and that consequently no letter of approval or approvability issued by the FDA is on file with the Commissioner of the TDH.

Dennis E. Baker testified that a letter (Exhibit 13) was sent to the Respondent on May 2, 1988. The letter advised the Respondent that his use of antineoplaston therapy constituted a violation of TEX.REV.CIV.STAT.ANN. art. 4476-5 §18 (Appendix B). The letter stated: "It is imperative that you cease your Antineoplaston Therapy until such time as you have been issued either a New Drug Approval (NDA), or an Investigational New Drug Approval (IND) by the Federal Food and Drug Administration. It is also essential that you cease advertising, or otherwise representing your Antineoplaston Therapy as having any effect in the treatment of cancer." A copy of the letter was sent to the Texas State Board of Medical Examiners. (Tran. 47).

Mr. Baker testified that Exhibit 13 was precipitated by persons appearing on the Sally Jessy Raphael television show

and championing the Respondent's treatment for cancer. That show resulted in numerous calls to the TDH seeking information about the Respondent. (Tran. 49-50, 82-83). TDH did not seek further administrative or legal action against the Respondent following the warning letter dated May 2, 1988, until 1992. In 1992, TDH filed suit seeking to enjoin the Respondent from producing and prescribing antineoplastons and seeking to destroy his stock of product. TDH filed the suit after determining that the Board of Medical Examiners was not acting quickly enough against the Respondent. (Tran. 96-97). Dennis Baker testified that in his opinion §5.09 of the Texas Medical Practice Act did not apply to the Respondent's use of antineoplastons to his patients because §5.09 does not specify that the physician may use an unapproved drug. (Tran. 100).

Pursuant to Exhibit 30, antineoplastons A2, A3, A5, A10, and AS2-1 are "drugs" within the meaning of 21 U.S.C. §321(g) and "new drugs" within the meaning of 21 U.S.C. §321(p). (Appendix G).

No evidence was admitted, either by document or by testimony, that antineoplastons A, AS2-5 or AS-5 are "drugs" or "new drugs" as defined in 21 U.S.C. §321(g) and (p).

b. Respondent's evidence related to Charge IB

The Respondent introduced Section 5.09 (Appendix F) of the Medical Practice Act into evidence in support of his contention that he was authorized to administer antineoplastons to his patients as necessary to meet his patients' immediate needs.

The Respondent testified that most of his patients have cancer in one of its forms. Some of his patients have AIDS. Generally the Respondent's patients have failed to respond to radiation therapy and chemotherapy. Many have been informed by other medical facilities that their condition is terminal and no other conventional treatment is available The Respondent testified that antineoplastons are not a panacea or cure-all for cancer, but he has had patients who had been nonresponsive to any conventional treatment who have responded favorably to antineoplaston therapy. The Respondent testified that patients who discontinue antineoplaston therapy too soon have cancer recur because of microscopic accumulations of surviving cancer cells that can cause the cancer to form again.

The Respondent testified that patients removed from the treatment too soon will die. The Respondent testified that his antineoplaston therapy is, in his opinion, meeting the

immediate needs of his patients. He further testified that the treatment of every patient is involved in his research into the use of antineoplastons. (Tran. 162-170). He also stated that antineoplaston therapy is a form of chemotherapy. (Tran. 302).

M.M., mother of patient P.M., testified that her son was diagnosed at age 4 with a large mass in his brain. The tumor was a optic, hypothalamic astrocytoma which was too entwined for surgery. P.M. began antineoplaston therapy in April 1988. P.M. is now 12 years of age, is healthy and feels good. His physician is of the opinion that if P.M. is taken off antineoplaston therapy then P.M.'s tumor will grow again and P.M. will die. (Tran. 331341).

c. Analysis of the evidence relating to Charge IB

Charge IB covers the period from September 1, 1985, to August 31, 1989.

From September 1, 1985, until May 2, 1988, the Respondent's treatment of his patients with antineoplastons was authorized by the grant of permission from TDH as described in paragraph IV. B. 1 (c) above. On May 2, 1988, that permission was withdrawn and the Respondent was on notice that TDH considered his use of antineoplaston therapy after May 2, 1988, to be a violation of the law.

From May 2, 1988, until August 31 1989, the governing laws of the State of Texas included both §18 of the TFDCA and §5.09 of the Medical Practice Act. Section 18 required that before any person could sell, deliver offer for sale, hold for sale or give away any new drug, that drug must have been approved by the FDA and the approval not withdrawn, and a copy of the letter of approval or approvability must have been on file with the Commissioner of the Texas Department of Health. (Appendix B). Section 5.09 authorized any physician licensed in Texas to supply the needs of his or her patients with any drug which is necessary to meet the patients' "immediate needs", provided the physician was not allowed to operate a retail pharmacy without complying with the Texas Pharmacy Act. (Appendix F).

The first question is, "Does Section 18 of the TFDCA conflict with Section 5.09 of the Medical Practices Act, and if so, which controls?" If the Medical Practices Act controls, then the question arises, "Was the Respondent's treatment of his patients in conformity with Section 5.09?"

It is apparent that Section 5.09 grants broader authority to physicians than is allowed under Section 18. The statutes are in conflict.

Section 18 is a general provision of the law. It is directed to

all persons. Section 5.09 is a special provision of the law directed specifically to physicians licensed by the Texas State Board of Medical Examiners. Conflicts between general provisions and special provisions are controlled by TEX. GOV'T. CODE ANN. §311.026, which states, "(a) If a general provision conflicts with a special or local provision, the provisions shall be construed, if possible, so that effect is given to both. (b) If the conflict between the general provision and the special or local provision is irreconcilable, the special or local provision prevails as an exception to the general provision, unless the general provision is the later enactment and the manifest intent is that the general provision prevail"

Even though Section 18 was enacted later in time (September 1, 1985) than the applicable version of Section 509 (August 29, 1983) there is no evidence that the manifest intent of the legislature was that Section 18 prevail over Section 5.09.

Additional grounds for asserting that Section 5.09 prevails is found in the Medical Practice Act Section 1.02 wherein the legislature declared that formulating the Medical Practice Act to control the practice of medicine was considered necessary to protect the public interest. (Appendix F). (emphasis added).

The staff argues that the word "authorized" should be read into Section 5.09 in order to bring it into harmony with Section 18. When the Legislature later amended Section 5.09 in 1989, the

Legislature had the opportunity to insert the word "authorized" into the statute and did not do so. This Administrative Law Judge will not presume to insert language into the section which the Legislature has omitted.

Section 5.09 of the Medical Practices Act provides an exception to Section 18 of the TFDCA. The question of whether the Respondent's treatments comport with Section 5.09 remains.

The Board, on January 2, 1987, adopted rules found at 22 TAC §169.1 et seq, which provide guidelines in interpreting Section 5.09. Rule 169.2 defines "immediate needs" as "[t]he amount of a prescription drug needed for the proper treatment of a patient until access to a pharmacy is possible." (Appendix J).

The Texas Pharmacy Act, TEX.REV.CIV.STAT.ANN. art. 4542a-1, defines prescription drug" at Section 5 (41) as: "(A) a substance for which federal or state law requires a prescription before it may be legally dispensed to the public (B) a drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled ... (i) 'Caution: federal law prohibits dispensing without prescription'; or ... (C) a drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only."

The evidence relating to the issue of whether antineoplastons fall within the definition of "prescription

drugs" is meager. There was no evidence admitted that antineoplastons are required by federal or state law to be dispensed only pursuant to a prescription nor that they are required to be labeled with the specified caution. The Administrative Law Judge is left to infer from other evidence whether antineoplastons fall within the definition. The staff offered into evidence the deposition of the Respondent (Exhibit 16) in which Exhibit 2 includes a description of the administration of antineoplastons. That description states: "There are three different routes of administering Antineoplaston treatments: 1. Intravenous (I.V.) Infusions--through I.V. catheter and ambulatory pump; 2. Intravenous Injections--through I.V. catheter [and] 3. Orally, in capsule form ... The insertion of the catheter is a simple procedure performed by a qualified medical doctor outside our Clinic ... The preferable vein for this purpose is the one which runs in the upper part of the chest under the collar bone..." The Administrative Law Judge infers from the fact that two of the three routes of administration require the surgical insertion of a catheter into a patient's vein, that antineoplastons are thus restricted to use by a practitioner only and thus fall within the definition of prescription drugs.

In order to fall within the exception provided by Section 5.09 of the Medical Practices Act, the Respondent's use of antineoplaston therapy must be necessary to meet his patients' immediate needs The definition of "immediate needs" found in the Board's Rules at 22 TAC §169.2 is not wholly applicable inasmuch as antineoplaston therapy is not available except through the Respondent's clinic.

In regard to the matter of patients' needs, the Respondent testified that antineoplaston therapy was necessary for the survival of his patients. M.M., mother of P.M., testified that her son's physician is of the opinion that discontinuance of antineoplaston therapy for P.M. would allow the tumor in P.M.'s brain to resume growth resulting in the death of P.M.

The administrative Law Judge is at a loss to conceive of a need more immediate than survival. All other needs appear secondary. The Respondent offered evidence from experts whose opinion is that antineoplaston therapy is necessary for the survival of the Respondent's patients. The Staff did not offer expert testimony that would support a finding against the Respondent. Therefore, a finding that the Respondent's antineoplaston therapy, between May 2, 1988, and August 31, 1989, falls within the exception provided by Section 5.09 of the Medical Practice Act is justified.

The Staff failed to prove Charge IB by a preponderance of the evidence.

3. Charge IA

Part A of Count I alleges that the Respondent, from September 1, 1989, to August 14, 1992, administered antineoplastons including those designated A, A-2, A-3, A-5, A-10, AS2-1, AS2-5, and AS-5, to his patients without having the approval of the Federal Food and Drug Administration (FDA) pursuant to Title 21 U.S.C. Section 505 and without having a letter of approval or approvability on file with the Commissioner of Health, Texas Department of Health (TDH), in violation of the Sections 431.021 (B) and 431.114 (E) of the Texas Food, Drug and Cosmetic Act (the TFDCA).

Sections 431.021 and 431.114 are found in Appendix A

a. Staff's evidence related to Charge IA

The Respondent stipulated that he administered antineoplastons to his patients during the time specified in Count IA. The Respondent also stipulated that no formulation of antineoplastons has been approved for commercial, interstate marketing by the FDA pursuant to Section 505 of the Federal Act and that consequently no letter of approval or approvability issued by the FDA is on file with the Commissioner of the TDH. (Ex. 15)

Dennis E. Baker, testified that he is of the opinion that the Respondent's practice has violated the Texas Food, Drug and Cosmetic Act. (Tran. 33, 86). He further testified that the Department of Health filed suit against the Respondent in 1992 in order to permanently enjoin the Respondent from selling or prescribing antineoplastons and seeking to destroy the Respondent's stock of antineoplastons. (Tran. 96-97).

Pursuant to Exhibit 30, antineoplastons A2, A3, A5, A10, and AS2-1 are "drugs" within the meaning of 21 U.S.C. §321(g) and "new drugs" within the meaning of 21 U.S.C. §321(p). (Appendix G).

No evidence was admitted, either by document or by testimony, that antineoplastons A, AS2-5 or AS-5 are "drugs" or "new drugs" as defined in 21 U.S.C. §321(g) and (p).

b. Respondent's evidence related to Charge IA

The Respondent introduced Section 5.09 (Appendix F) of the Medical Practice Act into evidence in support of his contention that he was authorized to administer antineoplastons to his patients as necessary to meet his patients' immediate needs. The Respondent also introduced into evidence the Texas Intractable Pain Act (Appendix D) in support of his contention that he was authorized to administer antineoplaston to his patients while treating them for intractable pain.

Dennis E. Baker testified that antineoplastons are not listed in Schedules I through V or in Penalty Groups 1 through 4 of Chapter 481 of the Health and Safety Code. (Compare Appendix 1). He had no opinion whether antineoplastons are "dangerous drugs" (Appendix E) because he had no opinion whether they are unsafe for self-medication. (Tran. 66-72).

The Respondent's testimony set forth under Charge 1B above is applicable to charge IA as well. The Respondent further testified that many of his patients have terrible pain because of cancer. (Tran. 162-170).

Nicholas Patronas, M.D., Chief of the Section of Neuroradiology, National Institutes of Health, testified that he was a part of a group of six physicians and scientists who did a site visit at the Respondent's clinic to review his treatment of brain tumors. (Tran. 116). The site visit occurred October 4, 1991. (Exhibit 27). Dr. Patronas testified that, based upon his background, he is of the opinion that if antineoplaston therapy were to be withheld from the Respondent's brain tumor patients, Men the patients will die. (Tran. 124).

Fred J. Epstein, M.D., Certified by the American Board of Neurological Surgeons, testified by affidavit that he is of the opinion that some of his patients have undergone remission of other-wise untreatable brain cancer as a result of the

Respondent's treatment. Dr. Epstein stated: "Most importantly, patients refractory to approved therapy who have experienced partial regression or stabilization of brain neoplasms under Dr. Burzynski's treatment should most certainly be permitted to continue on the treatment. Any such patient whose treatment is discontinued will almost certainly experience tumor progression and will ultimately die." (Exhibit 44).

Ten patients testified on behalf of the Respondent. One of those patients was a medical doctor, a practicing plastic surgeon, who here is considered an expert for the purpose of expressing an opinion. Several witnesses testified and presented documents indicating that their personal physicians believe antineoplaston therapy, in their professional opinions, to be necessary for the patients' continued survival. The physician's are here considered experts for the purpose of expressing opinions.

Patient S.C. testified that she was diagnosed in March 1992 as having a glioblastoma multiform Grade IV brain tumor which was very aggressive and fast growing. She had surgery which did not remove all of the tumor. Surgery was followed by radiation therapy. She began antineoplaston therapy about August 1992. S.C. testified that the tumor is now gone.

S.C.'s surgeon has advised her to continue the antineoplaston therapy because if one cancer cell survives, it could cause the tumor to form again. (Tran. 309-314).

Patient T.M.H. is a medical doctor. He is a practicing plastic surgeon. He was diagnosed on Good Friday, 1992, as having non-Hodgkins lymphoma of the mediastinum, Grade IV. T.M.H. did not want to endure chemotherapy, radiation and bone marrow transplants because he had observed the results obtained. T.M.H. began antineoplaston therapy on June 1, 1992. He has continued to work as a plastic surgeon with no toxic sideeffects. T.M.H. was of the opinion that it was necessary for him to continue the treatment with antineoplastons. (Tran. 319-324).

As the previously discussed testimony of M.M. showed, her son's physician is of the opinion that P.M. will die if taken off of antineoplaston therapy. (Tran. 331-341).

D.M., son of a patient, testified that his father was diagnosed in June 1992 with a glioblastoma multiform Grade IV brain tumor. The patient underwent surgery which was unable to remove all of the tumor. Surgery was followed by high dose radiation and chemotherapy without results. The patient began antineoplaston therapy in September 1992. The patient's physician recommends that he continue the

antineoplaston therapy and is of the opinion that the patient will not long survive removal from the therapy. (Tran. 343-348).

Patient M.J.S. testified that she was diagnosed in February 1991 as having nonHodgkins low grade lymphoma. She was offered options of chemotherapy and radiation therapy or a bone marrow transplant. The chemotherapy and radiation would be expected to provide temporary remission while the bone marrow transplant was experimental and risky. M.J.S. began antineoplaston therapy in 1992. Her physician recommends that she continue the therapy. (Tran. 399-404).

c. Analysis of the evidence relating to Charge IA

The Respondent argued that the Texas Intractable Pain Treatment Act (Appendix D) provides authorization for his treatment of patients with antineoplastons. He further argues that the Texas Intractable Pain Treatment Act prohibits the Board from subjecting him to disciplinary action for using antineoplaston therapy on his patients. The Administrative Law Judge does not agree with the Respondent. There was insufficient evidence received to find that the Respondent has treated his patients for intractable pain. No witness, save the Respondent, mentioned pain. Further, the Respondent

contends that his antineoplaston therapy treats the cause, not the pain. Any pain reduction was a consequence of amelioration of the cause of the pain not a consequence of a pain treatment.

Charge IA covers the time period from September 1, 1989, to August 14, 1992. During that time period, Section 431.114 of the Government Code (Appendix A) and Section 5.09 (Appendix F) of the Medical Practice Act were both in effect. The current version of Section 5.09, which became effective June 1, 1989, and the codified version of the Texas Food, Drug and Cosmetic Act, which became effective September 1, 1989, were adopted during the same legislative session. The fact that the two were adopted by the same legislature lends additional credence to the contention that Section 5.09 provides an exception to the strict limits of Section 431.114 of the TFDCA.

The comments in Section V.B.(2)(c) above regarding the conflict between Section 18 of the TFDCA and Section 5.09 of the Medical Practice Act apply equally to the conflict between Section 43L114 of the TFDCA and Section 5.09 of the Medical Practice Act. Section 5.09 provides an exception to the strict limitations found in Section 431.114.

Again the Respondent provided evidence and testimony

from persons whose expert opinion was that antineoplaston therapy was necessary for the survival of certain of the Respondent's patients. The Staff did not counter that evidence with an opposing expert viewpoint. Consequently the evidence supports a finding that the Respondent's antineoplaston therapy between September 1, 1989, and August 14, 1992, falls within the exception provided by Section 5.09 of the Medical Practice Act.

The Staff failed to prove Charge IA by a preponderance of the evidence.

4. Charge ID

Part D of Count I alleges that the FDA, from February 13, 1984, to March 16, 1989, placed a "clinical hold" on the Respondent's study of antineoplaston A-10 but that the Responden, during the clinical hold, continued to administer antineoplaston A-10 to his patients in violation of Section 18(b) of the TDFCA.

a. Staff's evidence related to Charge ID

The Respondent stipulated that he administered antineoplastons to his patients during the time specified in Charge ID. The Respondent further stipulated, in regard to

Charge 11, that he treated the patients listed as alleged.

The Staff offered the Respondent's deposition (Exhibit 16) into evidence. On page 29 of the deposition, the Respondent admitted that prior to June 1983 he had filed a "Notice of Claimed Investigational Exemption for New Drug" for antineoplaston A-10 and that on February 13, 1984, he was informed by letter from the FDA, that "[u]ntil the above additional required information is received and you are told that we conclude that it is reasonably safe for you to initiate the trial, the study you propose may not be legally conducted under this IND." The Respondent confirmed at hearing that he filed an IND about May 6, 1983, and the clinical hold was released in 1989. (Tran. 161).

Exhibit 7, introduced into evidence is a letter, dated March 16, 1989, addressed to the Respondent from the FDA. Exhibit 7 states, "...we have concluded that it is reasonably safe to proceed with your proposed study. Consequently, the 'clinical hold' of this IND is removed. We note, however, that patients may only be treated under the submitted study titled 'Treatment of Advanced Breast Cancer with Antineoplaston AlO.' We have also enclosed a copy of 21 CFR Part 312 and ask that you pay particular attention to section 312.7(d)."

Pursuant to the Respondent's stipulation regarding Charge II, the Respondent treated the following patients with antineoplaston A-10 during the time of the "clinical hold" as alleged: J.P., J.K. (male), J.K. (female), S.H., D.B., B.S., S.J., A.D., L.S., C.M., J.H., S.Z., M.T., C.H., S.K., and E.F. None of this group of patients received treatment after May 2, 1988.

Additional evidence that the Respondent treated patients with antineoplaston A-10 during the time of the "clinical hold" as specified in Charge ID, is found in Exhibit 27, the review of brain tumor cases treated with antineoplaston A-10 and AS2-1. That document was prepared following the site visit from representatives of the National Cancer Institute on October 4, 1991. Exhibit 27 indicates that patients E.L., P.W., J.K., P.M., and H.M. were treated with antineoplaston A-10 between February 13, 1984, and March 16, 1989.

Pursuant to Exhibit 30, antineoplaston AIO is a "drug" within the meaning of 21 U.S.C. §321(g) and a "new drug" within the meaning of 21 U.S.C. §321(p).

b. Respondent's evidence related to Charge ID

The Respondent offered no specific evidence related to Charge ID other than copies of the statutes previously

mentioned. The Respondent was the source of Exhibit 27 which contains evidence indicating that antineoplaston A"10 as administered to patients during the alleged time period.

c. Analysis of the evidence related to Charge ID

The time period covered by Charge ID, February 13, 1984, until March 16, 1989, overlaps the time periods covered by Charge IB and IC. Section 18(b) (Appendix B) of the TFDCA was not effective between February 13, 1984, and September 1, 1985. Consequently, as to that period of time the Charge does not specify a violation of the TFDCA.

The time period additionally overlaps the time period during which the Respondent was treating patients with antineoplastons "it the permission of the Texas Department of Health. That permission ended on May 2, 1988.

Pursuant to Exhibit 27, between May 2, 1988, and March 16, 1989, the Respondent treated patients E.L., P.W., J.K., P.M., and H.M. with antineoplaston A-10.

The Respondent's stipulations do not specify that the Respondent treated patients with antineoplaston A-10 between May 2, 1988, and March 16, 1989.

As previously stated in regard to Section 18(a) of the TFDCA, Section 18(b) is likewise a general statute. It

precludes any "person" from specified acts. Section 5.09 of the Medical Practice Act is a special provision which grants authority to the licensees of the Board. That authority exceeds the limitations of Section 18(b) and is an exception to the limitations of Section 18(b).

Based upon the foregoing, the Administrative Law Judge is of the opinion that the Staff did not prove, by a preponderance of the evidence, its Charge ID.

C. Evidence and Analysis Related to Charge II

In Charge II, the staff alleged that the Respondent administered antineoplaston to 40 specific individuals between October 9, 1975, and April 7, 1987, in violation of the TFDCA Section 431.114 formerly TEX. REV. CIV. STAT. ANN. art. 4476-5 which constitutes a violation of Section 3.08(4)(A) of the Medical Practice Act.

a. Staff's evidence related to Charge II

The Respondent stipulated that he treated the patients listed in Charge II with antineoplastons as alleged.

b. Respondent's evidence related to Charge II

The Respondent offered no evidence specifically directed to Charge II, other than the statutes previously mentioned.

C. Analysis of the evidence related to Charge II

As previously stated in the analysis of the evidence related to Charge IB and Charge IC, the Respondent was advised by the Texas Department of Health that his manufacture and use of antineoplaston would not contravene the TFDCA. Such permission, given in 1977 extended until May 2, 1988, when it was withdrawn. During that period of time the manufacture and use of antineoplastons in the State of Texas was not in violation of TEX. REV. CIV. STAT. ANN. art. 4476-4 §16 or its successor TEX. REV. CIV. STAT. ANN. art. 4476-5 §18.

None of the patients listed in charge II were treated with antineoplastons after April 7, 1987. One of the patients, B.B., began treatment with antineoplastons prior to 1977. His treatment began on October 9, 1975, and extended to October 11, 1982. Such treatment, prior to 1977, falls within the exception contained in TEX. REV. CIV. STAT. ANN. art. 4476-5 §16(c) which excludes application of the prohibition for drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. (Appendix C).

Since none of the patients were treated after permission to

manufacture and use antineoplastons was withdrawn by the TDH, and since the sole patient treated before permission was given falls within the investigational exception, the Staff failed to prove by a preponderance of the evidence that the Respondent's use of antineoplastons to treat patients between October 9, 1975, and April 7, 1987, was in violation of the TFDCA as alleged in Charge 11.

Additional grounds for finding that the Staff failed to prove Charge 11 is found in the analysis of the conflict between Section 5.09 of the Medical Practice Act, which became effective on August 5, 1981, and the TFDCA. Such analysis has been previously set forth in Sections V.B.(2)(c) and V.B.(3)(c) above.

D. Evidence and Analysis Related to Charge III

Charge III alleged that from September 1, 1985, until August 14, 1992, the Respondent, through promotional literature, writings and publications represented to the public that antineoplastons affect human neoplasms in violation of TFDCA Section 431.183(a)(2) which constitutes a violation of Section 3.08(4)(A) and 3.08(6) of the Medical Practice Act.

a. Staff's evidence related to Charge III

The Staff offered into evidence Section 431.183 of the

TFDCA (Appendix A). The Staff also offered into evidence Exhibit 33, a brochure of Burzynski Research Institute, Inc. and Exhibit 16, the deposition of the]Respondent taken on April 27, 1993.

The exhibits attached to Exhibit 16 include:

Deposition Exhibit 2, an informational brochure in use by the Burzynski Clinic. The brochure contains the following statements: "Over 25 years ago, Dr. Burzynski discovered peptides and amino acid derivatives in our body that control cancer, not by destroying cancer cells, but by correcting them. He named these substances Antineoplastons ... Dr. Burzynski discovered in 1967 that our body can and does direct these potential cancer cells back onto their normal path through Antineoplastons that bond to cancer cells, feeding them the complex information they need to normalize and fulfill their original function ... The front page of the July-August 1990 issue of Oncology News featured an article on Antineoplastons, 'a completely new type of antitumor agent that is nontoxic and seems to make malignant cancer cells revert to normal.'...Clinical results on Antineoplastons in patients oil cancer refractory to other forms of therapy included reports of complete remission from Japan and the USA in inoperable metastatic ovarian carcinoma and advanced

stage prostate cancer respectively. The most impressive results with Antineoplastons have been in brain tumors (astrocytoma and glioblastoma), and advanced cancer of the prostate."

Deposition Exhibit 3, an article entitled "Future Trends in Chemotherapy" by Patricia Leeson in Drug News and Perspectives, The International Drug Newsmagazine, May, 1988.

Deposition Exhibit 4, an article entitled "The Anticancer Effect of Antineoplaston A-10 on Human Breast Cancer Serially Transplanted to Athymic Mice" by Ken Hashimoto, Toshiharu Shintomi, Maki Tanaka and Teruo Kakegawa, the lst Department of Surgery Hideaki Tsuda, Department of Anesthesiology; and Hiroshi Hara, the 2nd Department of Surgery, Kurume University School of Medicine, in The Journal of Japan Society for Cancer Therapy, January 20, 1990.

Deposition Exhibit 5, an article entitled "Chemopreventive Effect of Antineoplaston A-10 on Urethane-induced Pulmonary Neoplasm in Mice" by Naofumi Eriguchi, Hiroshi Hara, Hiroaki Yoshida, Hiroyuki Nishida, Tosllimichi Nakayama and Kiroku Ohishi, the 2nd Department of Surgery and Hdeaki Tsuda, Satoshi Inoue and Izumi Ikeda, Department of Anesthesiology, Kurume

University School of Medicine, in The Journal of Japan Society for Cancer Therapy, July 20, 1988.

Deposition Exhibit 6, an article entitled "Antineoplastons: Nontoxic Chemotherapy" in Discoveries in Medicine, Winter 1991, published by the Research Division of Mutual Benefit Life, Robert W. Maver, Editor.

Deposition Exhibit 7, an article entitled "Antineoplastons: New Antitumor Agents Stir High Expectations" in Oncology News, July-August, 1990, no byline.

The Respondent testified in his deposition that he supplies the informational brochure (Deposition Exhibit 2) to prospective patients and provides to his patients, upon request, the publications described in Deposition Exhibits 3 through 7. (Deposition, pg. 46-81

The Respondent identified Exhibit 33 as a brochure used by Burzynski Research Institute, Inc. in 1986. He testified that the brochure is no longer used. (Tran. 240-244). Exhibit 33 contains the following statements: "The intent of this brochure is to increase public awareness of a new revolutionary concept in treating cancer victims ... Since 1967 we have been working on a new treatment for cancer which has shown great promise ... The majority of cancer

patients treated in our Institute showed positive response to treatment. The Institute is using now ten formulations of Antineoplastons. Each of these formulations was submitted initially to Phase I clinical trials. Phase I clinical studies of Antineoplaston A2 injections revealed that only 7% of patients did not have positive response to the treatment. The remaining patients responded to the treatment and obtained complete remission, partial remission or stabilization of the disease. It is not our intention to state that we have made the long-desired discovery of a cure for cancer. We have managed to demonstrate, however, that it is possible to obtain complete remission of certain types of cancer with antineoplaston treatments ... After years of experimentation, Antineoplaston therapy is producing longterm remission in a number of patients..."

The Respondent testified at hearing (Tran. 207-208, 241, 301) and by deposition (Ex. 16, pg. 48-49) that he charges fees for treatment with antineoplastons, though only about 50% of his patients fully pay for treatment. Some patients pay what they can, others pay nothing.

b. Respondent's evidence related to Charge III

The Respondent offered no evidence related to Charge III.

The Respondent argued that Count III violates the Respondent's constitutionally protected right to free speech insofar as it seeks to impose sanctions upon the]Respondent based upon his statements regarding his opinions, ideas, or findings regarding his discoveries, and that §431.183(a)(2) of the Health and Safety Code is unconstitutional insofar as it purports to prohibit pure speech and/or unreasonably restrict the dissemination of truthful commercial speech.

c. Analysis of the evidence related to Charge III

The Respondent is charged with violating Section 431.183 of the Health and Safety Code by advertising that Antineoplastons affect neoplasms Section 431.183 became effective on September L 1989. Exhibit 33 was in use by the Respondent in 1986 and is no longer in use. There was no evidence that Exhibit 33 as used during the time that Section 431.183 was in effect.

"Advertising" is defined in Section 431.002 of the Health and Safety Code. (Appendix A). Advertising must be a

representation, it must be disseminated by some means other than by labeling, and its purpose must be to induce, or be likely to induce, directly or indirectly, the purchase of the drug.

According to Section 431.183, advertising that a drug affects neoplasms is false advertising regardless of the truth or falsity of the claim. To constitute a violation of Section 431.183, and hence contravene the Medical Practice Act Section 3.08(4)(A), the Staff was required to show that the Respondent was responsible for, or directed dissemination of, the offending advertising.

The Respondent has been providing a brochure which represents that antineoplastons affect cancers. The Respondent additionally has distributed articles, produced by others, which represent that antineoplastons affect cancers. The distribution of the brochures and articles was done in the name of the Respondent's clinic and hence at his direction. Therefore the]Respondent has disseminated representations that antineoplastons affect neoplasms. The brochure and the articles have a single purpose, that is to induce persons with cancer to undergo treatment with antineoplastons. Since the Respondent charges for the treatments, the patients effectively purchase the drugs. As a consequence, the brochure and

articles constitute advertising under Section 431.002.

The representation that antineoplastons affect neoplasms constitutes a violation of Section 431.183.

The Staff charged that the violation of Section 431.183 of the Health and Safety Code constituted a violation of Section 3.08(4)(a) and (6) of the Medical Practice Act (Appendix F). Such is a violation of Section 3.08(4)(A). However, to constitute a violation of Section 3.08(6) there is required a showing that the advertising statement was false, misleading, or deceptive. There was no evidence adduced at hearing that antineoplastons have no effect on neoplasms. Consequently, no violation of Section 3.08(6) was shown.

The Respondent's argument that Section 431.183 unconstitutionally restricts his right to free speech is not accepted. The Respondent's use of the brochure and selected articles constitutes commercial speech which enjoys less protection under the Constitution than does pure speeches. The government may restrict commercial speech when the government's interest in doing so is substantial, when the restrictions directly advance the government's interests, and when the restrictions imposed are not unduly extensive Cramer v. Skinner (1991, (CA5 Tex) 931 F.2d 1020, cert. denied 112 SC 298. The Administrative Law Judge is of the

opinion that Section 431.183 treads dangerously close to the line, but does not cross it. The state has a legitimate interest in protecting persons suffering from terminal and debilitating diseases from undue pressures. Such persons, being in a critical plight, seek any treatment that offers them the slightest hope. They think it better to exhaust any possibility than to resign themselves to a fate that seems otherwise certain. Section 431.183 protects such persons from advertising which may unduly raise hopes while providing other avenues by which such information may be disseminated among medical professionals. Section 431.183, therefore, appears constitutional.

E. Evidence and Analysis Related to Charge IV

In Charge IV, the Respondent is charged with collecting a fee for antineoplastons in violation of 21 CFR §3117(a) and (d) (Appendix K) which is alleged to be a violation of Section 3.08(4)(G) of the Medical Practices Act (Appendix F).

a. Staff's evidence related to Charge IV

Dennis E. Baker testified that it is his understanding that the Respondent charges a fee for treatment with antineoplastons, but Mr. Baker did not know what the charge

was. (Tran. 66-67).

The Respondent testified that he charges his patients for treatment with antineoplastons. Patients with AIDS pay $20.00 per day if they are able. Most AIDS patients are treated without charge. Brain cancer patients are charged $5000 to begin treatment. Patients with prostate cancer are charged approximately $500 per month for treatment. (Tran. 207).

The brochure in use by the Respondent's clinic (Exhibit 2 attached to Exhibit 16) indicates that a $5OOO deposit is required of all cancer patients. For patients placed on antineoplaston I.V. therapy, an additional $2,500 per month is charged beginning with the second month of treatment. AIDS patients pay no initial deposit, but are charged $20 per day for treatment. The brochure then lists various doses of antineoplastons which vary from $20 per day to $685 per day wit the majority of patients falling in the range of $135 per day to $315 per day. There is no specific charge listed for antineoplaston A10 capsules.

b. Respondent's evidence related to Charge IV

The Respondent testified that clinical trials under his INDs have not begun due to lack of funding. (Tran. 162, 206). Because antineoplastons have not been approved by the FDA, the Respondent can not sell them to drug companies or other doctors. The

Respondent is still investigating the uses of antineoplaston and publishing his results. Every patient being treated by the]Respondent provides information for his research. (Tran. 167). The Respondent has located a physician to be the clinical investigator for the Respondent's IND #22,029, a study of the use of antineoplaston A10 capsules in the treatment of advanced breast cancer. The investigator estimates that the cost of the clinical trial to be approximately $600,000. (Tran. 205).

The Respondent has a second IND, #40,576, which provides for a study of the use of antineoplaston AS2-1 capsules in the treatment of persons infected with HIV (Exhibit 2 to Exhibit 16). No evidence was offered regarding whether a clinical investigator has been located to conduct the study.

The Respondent also testified that approximately one-half of his patients fully pay for their treatment Some patients pay nothing. The Respondent has never turned a patient away for lack of money and has never sued a patient for a fee. (Tran. 301).

c. Analysis of the evidence related to Charge IV

Charge IV alleges that the Respondent's charges for antineoplaston treatment is in violation of 21 C.F.R. §312.7(a) and (d) and thus is in violation of Section 3.08(4)(G) of the Medical Practice Act.

The cited section, 21 C.F.R. §312.7(a) and (d), prohibits the promotion of an investigational new drug as safe and effective and the charging for an investigational drug in a clinical trial under an IND. The Respondent testified that the clinical trials under his INDs has not begun. Therefore, any fees charged by the Respondent are not fees for an investigational drug & a clinical trial under an IND. The Staff has failed to establish an essential element of its Charge IV.

Section 3.08(4)(G) of the Medical Practice Act condemns "persistent and flagrantly overcharging or overtreating" of patients. The charge against the Respondent is thus related to the fee charged his patients. To support a Ending that the Respondent persistently and flagrantly overcharged his patients requires evidence regarding the limits on reasonable charges for cancer treatment and for treatment of persons infected with HIV. There was no evidence indicating what a reasonable charge should be, and hence no proof that the Respondent's fees constituted persistent or flagrant overcharging.

Based upon the foregoing, Charge IV has not been proven by a preponderance of the evidence.

VI. Summary

The scope of the case is limited. Essentially the Respondent was charged with violating the Texas Food Drug and Cosmetic Act by using antineoplastons without FDA approval and by representing that antineoplastons "affect neoplasms." The Respondent was also charged with persistently and flagrantly overcharging his patients for antineoplaston treatments. The Staff had the burden of proving each of the elements of its allegations against the Respondent by a preponderance of the evidence.

The pleadings of the Staff, described in Section IV of this proposal (Positions of the Parties), specify the violations the Respondent is alleged to have committed. The pleadings limit the evidence that may receive consideration and the violations of law that may be addressed. Consideration of any other matters against the Respondent would violate the Respondents right to fair notice of the charges against him. For that reason the Staff's attempt to show the Respondent to be at fault for not appearing to go forward with the clinical trials under his INDs received no consideration.

In the same vein, this hearing has no authority to pass on the efficacy of antineoplastons. At the present time that is a matter for the consideration of the FDA. The attempts by the

Respondent to raise the efficacy issue therefore were fruitless as well.

The Staff has failed to prove by a preponderance of the evidence that the Respondent's use of antineoplaston therapy, wholly inside the State of Texas, without FDA approval is a violation of the Texas Food, Drug, and Cosmetic Act. If such action had been a violation of the TFDCA prior to May 2, 1988, the violation was permitted by the Texas Health Department. Following May 2, 1988, the actions of the Respondent were allowed under the exception provided by Section 5.09 of the Medical Practice Act. As a result, Charges IA, IB, IC, ID, and 11 were not proven against the Respondent.

The Staff has shown by a preponderance of the evidence that the Respondent's "advertising", written material disseminated by the Respondent, asserts that antineoplastons affect neoplasms and therefore is & violation of the Texas Health and Safety Code §431.183(a)(2) and the Medical Practice Act §3.08(4)(A). It is not a violation of §3.08(6) of the Medical Practice Act because there was no evidence that the "advertising" was false.

The staff has failed to prove by a preponderance of the evidence that the Respondent has charged a fee for antineoplaston treatment

in a clinical trial under an IND. The Staff has further failed to prove that the Respondent has persistently and flagrantly overcharged his patients for antineoplaston treatments. Charge IV has not been proven against the Respondent.

VII. Recommendation

The Respondent has been shown to have violated the prohibition against averring that a product affects cancer. It is a violation which is fairly simply remedied.

The Administrative Law Judge recommends that the Board of Medical Examiners issue an Order (directing the Respondent to Cease and Desist from disseminating advertising, as defined in the Health and Safety Code §431.002, which represents that antineoplastons affect neoplasms as prohibited by the Health and Safety Code §431.183.

[Findings of Fact and Conclusions of Law incorporating the Judge's decision, and appendices to the decision are omitted.]